

Attorney Docket No.: SJ-0005
Inventors: Danks et al.
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REMARKS

The Examiner has made a restriction requirement under 35 U.S.C. §121 as follows: Group I, claims 1-6 and 8-11 drawn to polynucleotides encoding carboxylesterase and vectors and host cells comprising these polynucleotides, classified in class 435, subclass 252.3; Group II, claim 7 drawn to a carboxylesterase classified in class 435, subclass 197; Group III, claims 12-14 and 18, drawn to methods of inhibiting tumor growth, classified in class 514, subclass 44; Group IV, claims 15 and 16 drawn to methods of inhibiting tumor recurrence, classified in class 514, subclass 44; Group V, claim 17, drawn to a method of purging bone marrow cells, classified in class 435, subclass 372; Group VI, claims 19 and 20 drawn to methods of identifying drugs activated by a carboxylesterase, classified in class 435, subclass 19; Group VII, claim 21 drawn to a modified promoter, classified in class 536, subclass 24.1.

The Examiner suggests that Groups I through VII are distinct each from the other. Specifically, the Examiner suggests that the DNA of Group I, the promoter of Group VII and the proteins of Group II are patentably distinct compounds because they are chemically different, and that the DNA has other utility besides encoding the proteins such as a hybridization probe and the proteins can be made

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by another method such as isolation from natural sources or chemical synthesis.

It is further suggested that Group I and Groups III-VI are related as product and process of use, and that the DNA of Group I can be used to produce the proteins of Group II. The protein of Group II and the promoter of Group VII are suggested to be unrelated to the methods of Groups III-VI as they are neither used nor made by the methods of these groups. The methods of Groups III-VI are suggested to be patentably distinct as they comprise unrelated steps and produce different results. Applicants respectfully traverse this restriction requirement.

The criteria which must be met for a restriction requirement to be proper are set forth in MPEP §803 and include: (1) that the inventions be independent or distinct and (2) that there would be a serious burden on the Examiner if the restriction is not required. MPEP 802.01 defines "distinct" to mean that the "two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made there, etc., but are capable of separate manufacture, use, or sale, as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER." Clearly Groups I, II, III, IV, V, VI, and VII which each contain claims with the same

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elements or technical features, namely, an isolated polynucleotide encoding a carboxylase capable of metabolizing a chemotherapeutic prodrug and inactive metabolites thereof, do not meet this definition of distinct.

Further, there would be no a burden on the Examiner due to additional searching, if the restriction is not made. Clearly any search performed to identify art relating to an isolated polynucleotide encoding a carboxylase capable of metabolizing a chemotherapeutic prodrug and inactive metabolites thereof, would identify any relevant art to claims set forth in Groups I-VII.

Accordingly, since the instant restriction requirement fails to meet either of the two criteria for proper restriction, withdrawal of the requirement is respectfully requested.

In an earnest effort to be completely responsive, however, Applicants elect to prosecute Group III, claims 12-14 and 18 drawn to methods of inhibiting tumor growth, with traverse.

Respectfully submitted,

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